DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 31, 2015

Z-systems Ag
c/o Ms. Linda Schulz
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K150021
Trade/Device Name: Z5m(t)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 29, 2015
Received: July 1, 2015

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150021

Device Name

Z5m(t)

Indications for Use *(Describe)*

Z5m(t) implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. The Z5m(t) implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Z-Systems AG

Z5m(t)

July 23, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name	Z-Systems AG Bittertenstrasse 15 CH-4702 Oensingen Switzerland Telephone +41 62 388 69 69 Fax +41 62 388 69 70
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Z5m(t)
Common Name	Dental Implant
Classification Name	Implant, endosseous, root-form
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INDICATIONS FOR USE

Z5m(t) implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. The Z5m(t) implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.

PREDICATE AND REFERENCE DEVICES

Z-Systems AG submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Z5m(t) is substantially equivalent in indications and design principles to the following legally marketed devices:

Primary Predicate

Z-Systems AG, Z-Look3 Evo SLM, K120793

Reference Devices

Z-Systems AG, Z5c, K132881; and

Implant Direct Sybron Manufacturing LLC, Legacy3 6 mm Length Implants, K131097.

DEVICE DESCRIPTION

Z5m(t) is a one-piece, root-form, threaded implant made from yttria-stabilized zirconia (Y-TZP). It has a tapered implant body, a double thread design in the coronal third of the implant and a self-tapping apex. The Z5m(t) endosseous surface is laser modified, identical to the Z5m surface cleared under K120793. Z5m(t) and Z5m utilize the same prosthetic components. Z5m(t) is designed for single or multiple tooth restorations and provided in two diameters (4.0, and 5.0 mm), each in three lengths (8, 10, and 12 mm). The Z5m(t) implant system is suitable for patients with metal allergies and the chronic diseases resulting from them.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation according to ISO 14937 *Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*; Biocompatibility evaluation according to ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*; software validation; and static and dynamic compression-bending testing according to ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants*.

- Sterilization parameters have been validated to an SAL of 10^{-6}.
- No new biocompatibility testing has been performed, as the materials and manufacturing methods used for the subject device are identical to those used for the predicate device.
- The subject device does not represent a new worst case in mechanical testing.
- No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Comparison	Subject Device	Primary Predicate Device	Reference Devices	
	Z-Systems AG Z5m(t)	Z-Systems AG Z-Look3 Evo SLM K120793	Z-Systems AG Z5c K132881	Implant Direct Sybron Manufacturing LLC Legacy3 6 mm Length Implants K131097
Indications for Use	Z5m(t) implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. The Z5m(t) implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.	Z-Look3 Evo SLM implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. The Z-Look3 Evo SLM implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.	Z5c implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5c implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them. Z5c implants are intended for delayed loading.	Lcgacy3 6mm Length consists of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
Design	One-piece, implant/abutment	One-piece, implant/abutment	Two-piece, implant/abutment	Two-piece, implant/abutment
Implant Diameter, mm	4.0, 5.0	3.6, 4.0, 5.0	4.0, 5.0	3.7, 4.2, 4.7, 5.2, 5.7, 7.0
Implant Length, mm	8, 10, 12	8, 10, 11.5, 13	8, 10, 12	6
Material				
Implant, Abutment	Y-TZP Laser treated surface	Y-TZP Laser treated surface	Y-TZP Laser treated surface	Titanium

This submission expands the Z-System Implant line to include a tapered version of the Z5m (previously named Z-Look3 Evo SLM) originally cleared in K120793. The modification includes a tapered implant body, a double thread design and a self-tapping apex. The primary predicate has a straight body and a single thread design. Both the subject device and the predicate device have the same abutment portion of the one-piece implant.

Z5m(t) diameters and lengths are the same as the reference device Z5c implant diameters and lengths cleared in K132881. The implant body, thread design and self-tapping feature of the Z5m(t) are substantially equivalent to the design of the reference device Legacy3 implant cleared

in K131097. Z5m(t) is different from the reference devices in that it is a one piece implant and abutment, where the reference devices are a two-piece implant and abutment configuration.

The subject device and the predicate and reference devices have the same intended use, the same technological characteristics, and encompass the same range of physical dimensions and characteristics, including implant diameter, length, and surface treatment.

CONCLUSION

Overall, the subject device has the following similarities to the predicate and reference devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above.